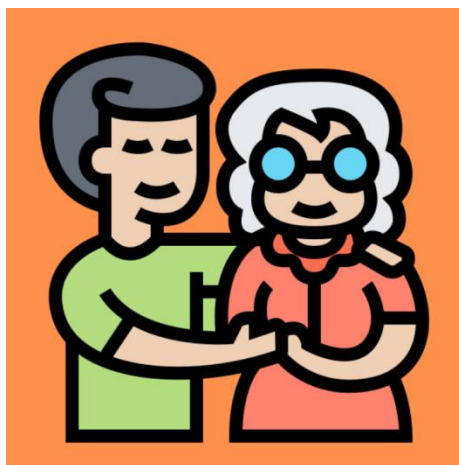


P23 Laboratories Self-Collection COVID-19 PCR Testing Standard Operating Procedure **COVID-19**

The Tennessee Department of Health has created a COVID-19 resource booklet for facilities to use for guidance on using P23 Labs self-test kits



last edited: November 5, 2020

Contents

Important Background Information	3
Step 1. Complete the Memorandum of Understanding (MOU)	4
Step 2. Request Testing Supplies.....	4
Step 3. Request access your facility's P23 Labs portal.....	5
Step 4. Receive Testing and Shipping Supplies	6
Step 5. Prepare for Pre-registration	7
Step 6. Register specimens for testing.....	8
Step 7. Order Test for Registered Patient.....	10
Step 8: Collect Samples for Testing.....	13
Step 9: Confirm Shipping Supplies.....	15
Step 10: Order Shipping Labels	15
Step 11. Ship Specimen(s) to P23 Labs	17
Step 12: What happens after I send my samples to P23?.....	18
Step 13. Accessing Results from P23 Portal.....	18
Step 14. Informing Patients about their COVID19 results	20
Step 15. Billing and Payment.....	20
Addendum	21
1. MOU.....	21
2. Biohazard label.....	21
3. Printable Instructions for Sample Collection (English & Spanish).....	21

Important Background Information

Document Purpose:

This Standard Operating Procedure (SOP) will guide you in the process of requesting and utilizing the P23 Laboratories COVID-19 Self-Collection PCR Test kits that have been provided to you by the State of Tennessee. If you are using testing kits from any other manufacturer, please refer to the guidance for the use of that product.

Intended Audience:

This Standard Operating Procedure (SOP) is intended for facilities who receive P23 Laboratories COVID-19 Self-Collection PCR Test kits from the Tennessee Department of Health. If you are using testing kits from any other manufacturer, please refer to the guidance for the use of that product.

Facility Responsibilities

It is the responsibility of the receiving agency to properly store the test kits that have been provided. These kits do not require refrigeration but should be protected from extreme temperatures. These kits are to be used for the self-collection of nasal specimens or saliva samples for COVID-19 PCR testing.

Saliva testing may only be used for individuals ages 2 years and older who can complete the procedure without assistance. There is no age restriction for the use of nasal swabs. Nasal swabs may be used for nasopharyngeal, mid-turbinate, or nasal collection. It is the responsibility of the receiving agency to ensure that registration, collection, and shipping processes and procedures are followed according to the guidance laid out in this document and the instructions provided by P23 Laboratories.

For any questions, please reach out to covid19.testing@tn.gov or covid.laboratory@tn.gov

Procedures for P23 Laboratories COVID-19 Self-Collection PCR Test kits

Step 1. Complete the Memorandum of Understanding (MOU)

- A. Your organization must complete and return the attached Memorandum of Understanding, in which the organization agrees to abide by the policies and procedures, as described
 - o A copy of the MOU can be found as an addendum to this document or it can be requested by emailing COVID19.testing@tn.gov.
- B. Return the signed MOU to COVID19.testing@tn.gov.
- C. Please complete and return the MOU before ordering supplies.

Step 2. Request Testing Supplies

- A. Qualifying organizations may request test kits by completing the survey found here: <https://arcg.is/1GPiOa>. If the survey will not load, use an alternate internet browser (internet explorer does not support this application)
- B. Enter the facility type and county location of the facility
- C. Choose from the dropdown list of qualifying entities. If your organization is not listed, email COVID19.testing@tn.gov to request approval.
- D. Provide point of contact name, phone number, and email. The shipping address is pre-populated and should reflect the address to which the kits should be shipped. If the address needs to be changed, email COVID19.testing@tn.gov
- E. Please order no more than a 30 day supply. If you need additional supplies, please complete the survey another time.
- F. How to use survey link: <https://arcg.is/1GPiOa> to request P23 supplies
 - o Select "P23 Nasal Self-Collection Test Kit" or "P23 Saliva Self-Collection Test Kit"
 - o Select the quantity needed (nasal kits come in boxes of 50, saliva kits come in boxes of 200)
 - o List the intended use of the kits (student health, employee testing, testing event, etc)

- Forecast the number of tests you anticipate will be used in the next 30 days
 - Provide the number of nasal swab kits and saliva test kits currently in stock
 - Provide any additional information you feel we should have in order to complete this request (e.g., if you have 200 kits on hand but have a testing event planned for 300 people, explain that you need an additional 100 kits to meet that capacity)
 - Click submit
- G. Receiving Confirmation on your order
- The email address provided will receive a confirmation of the placement of the request. If you do not receive a confirmation in 48 hours, please email COVID19.testing@tn.gov
- H. Shipping Timeline
- Note: Requests placed prior to 5pm CST Wednesday will be shipped on Thursday. Requests placed after 5pm CST Wednesday will ship the FOLLOWING Thursday.
 - Expect to receive kits within five business days from the day supplies were shipped.
 - If test kits are needed urgently, email COVID19.testing@tn.gov for assistance
- I. If you have any questions, please reach out to COVID19.testing@tn.gov

Step 3. Request access your facility's P23 Labs portal

- A. Once your facility has ordered supplies, please confirm that you have login access to the P23 TN Portal.
- Visit <https://p23labs.com/tn> and click on "FDA Authorized COVID-19 Provider Login for Results and Ordering". (see screenshot below)
 - Enter your username and password.



B. If you do not have a username and password, please email COVID19.testing@tn.gov and sandrine@p23labs.com with the following information:

C. Sample Email:

Hello COVID Testing and P23,

I have ordered P23 supplies through the Tennessee Department of Health/ TEMA. Please create a P23 TN portal account for me. Below is my information:

- Facility Information
 - Facility Name:
 - Facility Address:
 - Facility Phone Number
- Facility Contact Information
 - Contact Name:
 - Contact Phone Number:
 - Contact email:

D. Your facility will receive a unique User ID and password for your P23 online dashboard.

E. Portal information should only be shared with those who should have access to ALL patient lab results

F. Expected Turn Around time for portal access: 72 hours (3 business days)

- If you do not receive portal login information in 3 business day, email COVID19.testing@tn.gov , & COVID.Laboratory@tn.gov and sandrine@p23labs.com.

Step 4. Receive Testing and Shipping Supplies

A. Test kits will be shipped to the address provided in the online request form

B. Test kits must be protected from extreme temperatures.

C. Respond to the verification email received after the online Survey123 request for kits and verify the quantity received. Failure to verify receipt may result in delay of future shipments.

D. Expected Shipments

- Please note that if you order P23 nasal swabs you will get two shipments: one from P23 with the test kits and one from TEMA with the shipping supplies.
- If saliva kits are ordered you will receive one shipment with both test kits and shipping supplies.

E. Expected Shipping Supplies

- You should receive test kits (nasal, saliva, or both, as requested), biohazard bags, UN3773 stickers for the shipping container, and shipping container(s).
- It is not necessary to use a special shipping container so long as a UN3773 sticker is affixed to the container and the specimen are packed correctly.

F. Preparation for Shipment

- P23 tests kits use FedEx for shipping needs. Facilities have the option of pick up from their facility or drop off at a FedEx location.
- Facilities may wish to identify the FedEx drop boxes near their location and determine the time of the last pick-up.

Step 5. Prepare for Pre-registration

A. Background Information about Pre-registration

- Please confirm portal access before registering patients. (see step 1)
- Facilities can pre-register their kits in preparation for testing.
- Pre-registration is highly recommended so that P23 can link specimens to reporting facility

B. Identify patient for testing (e.g., patient experiencing symptoms of COVID-19, employee required to have regular testing, voluntary testing at a vulnerable population testing event, cluster investigation, etc)

C. When can your facility pre-register?

- It can be done before testing has occurred.
- It can happen when the facility knows when the person is coming in for testing. (It does not have to be for same day as testing)

D. Items to Keep in Mind

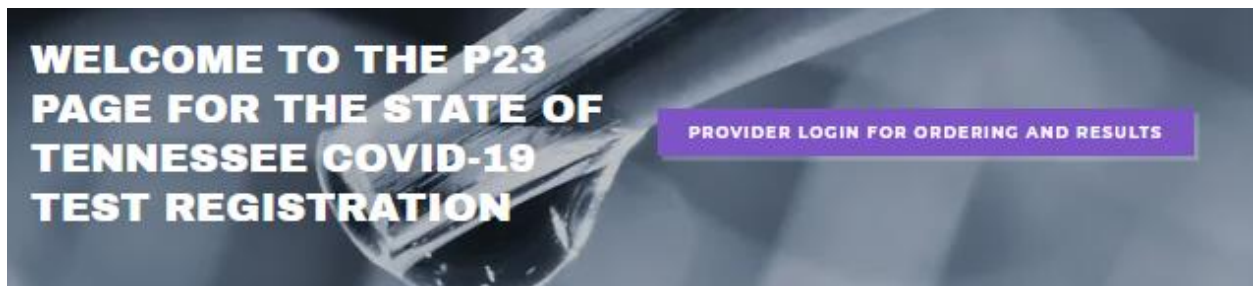
- Each sample has to be entered for pre-registration individually. A multiple sample option is not available. An excel sheet cannot be sent.

- After completing the pre-registration, please print the requisition and put one copy into the pocket of a lab sample biohazard bag. Print additional copies for your facility's records, as needed.

Step 6. Register specimens for testing

Please note that to ensure a smoother reporting experience, it is recommended that facilities use their portal and login information to pre-register samples. There have been some reporting issues and we hope that pre-registration through the portal with login credentials will make reporting smoother.

- A. Visit <https://p23labs.com/tn> and click on "FDA Authorized COVID-19 Provider Login for Results and Ordering". (see screenshot below)

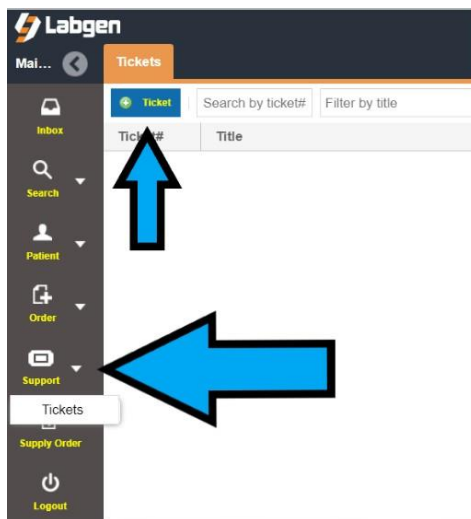
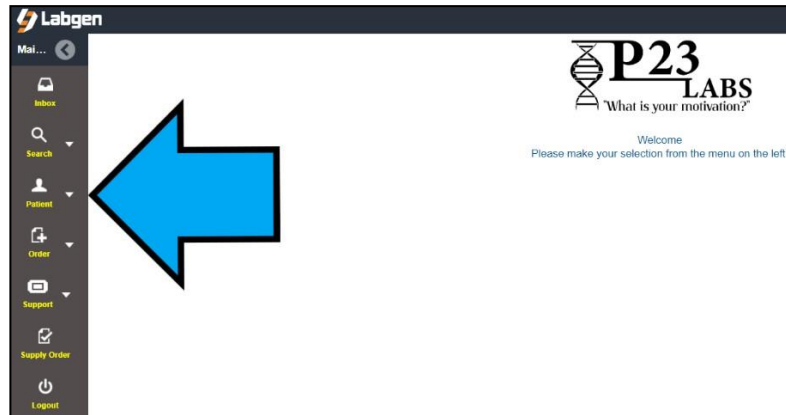


- B. Use your facility's P23 Labs User ID and Password to access your facility's dashboard.

Now, you register the patient

- C. From the menu on the left, click "Patient" and enter patient information
- "Chart Number" and "Room" are optional.
 - "Phone Number" is required. If the patient does not have a phone number, enter the facility's phone number.
 - Enter the patient's email if you would like the patient to receive an emailed copy of their results. (optional)
 - Choose your facility from the dropdown in "Patient Client".

- Only facilities associated with your organization should be on the drop down.
- If the facility name listed is incorrect, click “Support” and “Ticket” from the menu and click “+Ticket” to request a change. (You can still proceed with the patient registration and order)
- Click “Save”



D. Second, you need to fill in insurance section

- Neither the patient nor the facility will be billed for the processing of this test;
- In the upper left corner check the box next to “Same as Patient” to auto fill the patient information
- “Selected Insurance”: from the drop down, select “Bill Client”.

- The “Client” is the State of Tennessee
 - “Plan #” will automatically populate as “3”. Leave that alone.
 - The remainder of the insurance fields should be left blank.
 - Click “Save”

Now the patient is fully registered.


Now, you must order the test.

Step 7. Order Test for Registered Patient

E. Order the lab

1. Select “ORDER” and “Add Order” from the menu on the left and enter all or part of the patient’s name. Click on the refresh icon at the right side of the search bar.

ii.



The screenshot shows the Labgen application interface. On the left, a vertical menu contains icons for 'Inbox', 'Search', 'Patient', 'Order', and 'Logout'. The 'Order' menu is expanded, showing options: 'Add Order', 'Edit Order', 'Order Log', 'Standing Orders', and 'Dymo Listener Window'. A large blue arrow points to the 'Add Order' option. Below this, another screenshot shows the 'Add Order' screen. It features a search bar with 'Last Name' and 'First Name' fields, a 'Lab ID' field, and a 'Client ID' field. A refresh icon is on the right of the search bar. Below the search bar is a table of patients:

Name	PatiD	Sex	DOB	Client
TEST, M	R0000008080	F	01/01/1990	STATE OF TENNESSEE
TEST, M	R0000008065	F	10/05/1998	STATE OF TENNESSEE
TEST, MICHELLE	R0000008532	F	10/18/1988	MEMPHIS MENTAL HEALTH INS

A blue arrow points to the refresh icon in the top right corner of the patient list table.

2. Search the patient. Their information will auto populate to the order screen.
3. Select "Ord. Phy" from the drop down. This is a P23 physician which relieves you of the need to provide an ordering physician for the order.
4. Enter the collection kit's unique ID number in the "Cons. Phy." line
5. Change the order and collection dates and times, if needed.
6. At "Please select or type new source" choose "saliva" or "nasalpharyngeal" or type "nasal"
7. On the orange "test ordered" line enter "19" for the "Code", which denotes SARS-CoV2 COVID testing. Click the "+" to the right of the "Code" field to add the test, or press "Enter". The lab will then be listed below
8. Click "Submit" on the lower right of the screen
9. On the pop-up screen, enter the initials of the individual entering the order

The screenshot shows the 'Labgen' 'New House Call Order' form. Blue arrows indicate the following steps:

- Arrow 1: Points to the 'Patient(LF): TEST' field.
- Arrow 2: Points to the 'Ord. Phy:' dropdown menu.
- Arrow 3: Points to the 'Cons. Phy:' field.
- Arrow 4: Points to the 'Please select or type new source' dropdown menu.
- Arrow 5: Points to the 'Code' field in the 'Tests Ordered' table, which contains the value '19'.
- Arrow 6: Points to the 'Submit' button at the bottom right of the form.

The 'Tests Ordered' table shows the following data:

Code	Test Name	Spec.
19	SARS-COV2 (COVID19)	N/A

The 'Diagnosis Selected' section at the bottom has a 'Diag. Code' field and a 'Diag. Code' dropdown menu.

Now the test has been ordered for the patient.

- [illegible]

Step 8: Collect Samples for Testing

- A. Ask the patient to collect the specimen according to the P23 Labs instructions below. Please note that instructions in Spanish are available in the addendum.



IMPORTANT: Follow all directions carefully to ensure an adequate specimen is collected for testing.

Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva specimen. Do not remove the plastic film on the tube's funnel.

You can find additional guidance at:

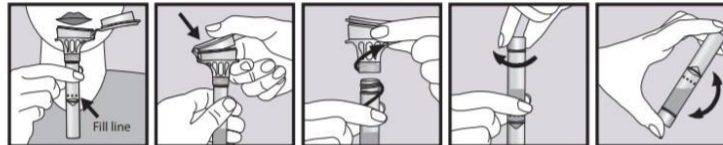
Collection steps: <https://www.dnagenotek.com/US/support/collection-instructions/omnigene-oral/om-505.html>

Collection video: <https://www.youtube.com/watch?v=l0bkXhjPVIU>

Step 1. Specimen collection

1. **IMPORTANT:** Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.
2. Open your P23 At-Home Covid-19 Test Collection Kit and place all of the contents on a clean, dry surface.
3. Remove the saliva collection device from its packaging and collect your specimen.

Read complete instructions prior to providing a saliva specimen.



1 Spit until the amount of saliva (not bubbles) reaches the fill line.

2 Close lid tightly by pushing down hard on the funnel lid until you hear a loud click.

3 Unscrew the funnel from the tube.

4 Use small cap to close tube tightly.

5 Shake the capped tube for 5 seconds.

Swab Instructions

Self-swab nasal specimen collection

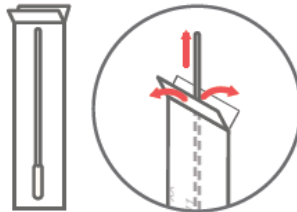
We know you aren't feeling well. Thank you for your participation. With your help, we want to understand whether people can test themselves for COVID-19 without assistance from a clinician.

These kinds of tests could one day become available for at-home swabbing for COVID-19 and other diseases like it. We appreciate your time and attention to the instructions below.

1 Open nasal swab

Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart (like you would to open a band-aid).

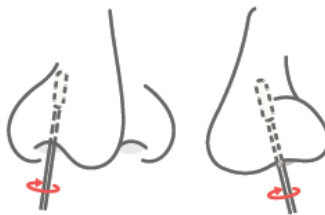
Be careful to only touch the handle, not the tip.



2 Swab nose

Gently insert the **entire** soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle around your nostril **4 times**.

Next, gently insert **the same swab** into the other nostril and rub it around the same way.

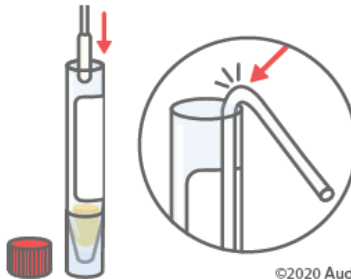


3 Put swab in tube

Lower the swab, tip first, into the provided tube.

Once the tip is at the bottom, break the swab handle at the top of the tube by bending back and forth.

Screw the red cap on tightly.



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Step 9: Confirm Shipping Supplies

- A. Confirm that your facility has adequate shipping supplies
 - 1. Shipping Supplies come from TN DOH/ TEMA.
 - 2. Supplies from TEMA include: biohazard bags, shipping boxes, and biohazard label
 - 3. Please note that the Biohazard UN3373 labels can also be printed from the SOP. A copy can be found as an addendum to this document.
 - 4. Each facility provides its own bubble wrap.
 - 5. If you ordered **P23 nasal kits**, your kits will come from P23 and the shipping supplies will come from TEMA.
 - 6. If you ordered **P23 saliva kits**, both kits and the shipping supplies will come from TEMA.
 - 7. If you have any questions about shipping supplies, please contact covid19.testing@com

Step 10: Order Shipping Labels

- A. When do I order a shipping label?
 - Labels need to be ordered the day of shipping or the previous day.
 - Labels can only be ordered M-F during regular business hours.
 - If your facility has a Saturday testing event
 - a. Ask for the label on Friday.
 - b. Pick-up is **not** possible on Saturday. Your facility will need to arrange drop off at a FedEx location.
 - If your facility has a Sunday testing event
 - a. You can order the label on Sunday and the label will be provided on Monday.
- B. How do I order a shipping label?
 - 1. Go to <https://p23labs.com/tn>
 - 2. Click on "Order Shipping Labels now" (screenshot below)



- a. What special items do I need to keep in mind?
 - a. Multiple test kits may be shipped in one box.
 - b. If you have multiple boxes, please add the number of boxes that you have to the comment box. You only need to fill out one shipping label request. P23 will send the number of labels you need.
 - c. By default, P23 will arrange for FedEx to pick up for shipment. If you prefer to drop them off at a FedEx location, please indicate in the notes.
- b. What happens after I submit my shipping label request?
 - a. Each facility will receive a confirmation email with the following items:
 - i. Shipping Label(s)
 - ii. Pick-up confirmation number
 - Pick-up confirmation number will be handy if you need to contact FedEx about logistic issues (e.g. If the pick-up is late, FedEx can track the truck and provide more information);
 - iii. Pick up time window. (all times CST)
 - iv. Tracking number for shipment
 - Tracking Number is very useful to track your shipment and confirm delivery to P23 labs. Please note that P23 labs does not take deliveries on Sunday.
 - b. Please print out the shipping label and attach to your pick up items.

- c. Expected Turn Around time: same business day
 - a. Within the same business day that the request is sent, each facility should receive shipping information. If you do not, please email sandrine@p23labs.com, isabel@p23labs.com, COVID19.Testing@tn.gov, & COVID.Laboratory@tn.gov.
 - b. Please note business hours are M-F 8A– 5P CST.

Step 11. Ship Specimen(s) to P23 Labs

- a. Ensure the screw top is secure on the specimen tube
- b. Write the patient's name on the specimen tube
- c. Place the specimen tube in a lab specimen biohazard bag and place the printed lab order in the front pocket of the biohazard bag. If the biohazard bag does not a front pocket, you can put the order in the biohazard bag.
- d. Place the bag(s) in the shipping container. You may pack as many specimens in the container as will fit.
 - a. FedEx directions for packaging of bio hazardous materials may be found here: https://www.fedex.com/content/dam/fedex/us-united-states/services/UN3373_fxcom.pdf
- e. Tape up the shipping container and affix the pre-paid mailing label from P23 labs.
 - a. If the shipping container is not marked UN3373, affix a UN3373 label to the package.
- f. Send specimens via FedEx
 - a. If you have chosen to have FEDEX pick up, please ensure all items are ready by the time indicated.
 - b. If you choose to drop off the items, find the closet FEDex drop-off. Specimens received by 10am at P23 labs will be processed within 24-48h.
 - c. Specimens are stable for up to seven days but should be shipped as soon as possible to ensure timely results.



Step 12: What happens after I send my samples to P23?

- a. All samples arrive at P23 labs with 2-day shipping. That timeframe is not included in providing results.
 - The facility can use the FedEx tracking number to see when the shipment was received by P23 labs.
- b. P23 Labs scans each shipment into their system.
 - Facilities do not have visibility into this step.
- c. Each sample is tested and all results are confirmed.
 - Facilities do not have visibility into this step.
- d. Results are uploaded to your portal**

Step 13. Accessing Results from P23 Portal

- a. Results should be available 48 hours after the samples are received at P23 Labs.
 - a. Please note: The P23 lab is not open on Sunday and that day is not included in the 48 hours turnaround time.
- b. Visit <https://p23labs.com/tn> and click on "FDA Authorized COVID-19 Provider Login for Results and Ordering". (see screenshot below)
 - a. If you need login help, reach out to Sandrine@p23labs.com or refer to Step 3.



- c. Click on "Inbox" at the top of the menu at the left of the screen
- d. Select the reports to view from the "Report" drop down
 - a. Complete = All completed results
 - b. Incomplete = Specimens that have been received at the lab but not yet processed
 - c. Critical = Specimens that were not processed due to being insufficient or unidentified
 - d. Abnormal = Positive results
- e. If you have access to multiple facilities, you may filter results by facility by choosing from the "Facility" drop down
- f. Results may also be sorted by client, report date, or collection date by clicking on the three bars in the upper right corner of the screen
- g. Reports may be selected for printing individually or in batches.
- h. Click "Remove Selected Reports as Printed" to remove reports from the inbox.
 - a. This will NOT permanently delete the reports.
 - b. They can still be found by clicking "Search" on the menu to the left of the screen and selecting "Search Reports"
- i. Please note if you experience reporting delays, follow the instructions below.
 - a. If it has been more than 48 hours from when the samples were received at P23, please reach out to Sandrine and ask for assistance.
 - b. Email sandrine@p23labs.com, COVID19.Testing@tn.gov, & COVID.Laboratory@tn.gov

- c. In your email, include:
 - i. Include First Name, Last Name and DOB of one specimen
 - ii. Facility Name and Facility contact
- j. Expected Turn Around time: 48 hours from when samples are received at P23 Labs
 - a. Each facility can check FedEx Tracking number to see when the package arrived at P23 labs.
 - b. If you have issues, please email sandrine@p23labs.com, COVID19.Testing@tn.gov, & COVID.Laboratory@tn.gov.
 - c. Please note: The P23 lab is not open on Sunday and that day is not included in the 48 hours turnaround time.

Step 14. Informing Patients about their COVID19 results

a. Your facility is responsible for informing patients of their results

- b. Tennessee Department of Health receives all test results via electronic laboratory reporting (ELR) and will also attempt to contact patients who have positive test results

Step 15. Billing and Payment

- a. P23 Labs test kits and processing are provided at no charge by the state of Tennessee and funded by federal COVID-19 relief funding
- b. Facilities are not to bill students for the cost of these tests
- c. Facilities will not receive an invoice from P23 labs; the State is billed directly

Addendum

Items included in Addendum:

1. MOU
2. Biohazard label
3. Printable Instructions for Sample Collection (English & Spanish)

COVID-19 Testing Supplies

Memorandum of Understanding (MOU)

INSTRUCTIONS

Complete this form in its entirety and return via email at COVID19.Testing@tn.gov.
If an organization has multiple locations that are to be supplied with COVID-19 testing supplies covered by this MOU, please list the facility name, address, and primary point of contact for each location on the additional page provided.
All fields are required.

ORGANIZATION

Name of Organization, Facility, or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

☐ Check here if multiple locations from one organization are to be supplied with COVID-19 testing supplies covered by this MOU. If so, please list the facility name, address, and primary point of contact for each location on the additional page provided.

_____ Number of associated locations that are to be supplied with COVID-19 testing supplies covered by this MOU.

MEDICAL DIRECTOR

Medical Director (or equivalent) of organization, facility, or practice must have an active and unencumbered TN medical license. Write N/A if this organization does not have a medical director)

Name

Credentials

Title

TN Medical License Number

National Provider Identifier (NPI)

E-mail

POINT OF CONTACT (POC)

Point of Contact (POC) is the person completing this MOU on behalf of the organization, facility, or practice.

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail

AGREEMENT OF UNDERSTANDING

The State of Tennessee, through federal COVID-19 relief funding, has procured COVID-19 testing supplies to provide to certain Tennessee agencies for the purpose of performing testing on symptomatic individuals and for limited surveillance testing. In accepting the statements below, this organization (and associated facilities) agrees to abide by the following guidelines in exchange for being provided these testing supplies.

Please indicate your agreement to each of the conditions by checking "Accept" beside each statement.

The requesting organization and associated facilities agrees to:

- ☐ Accept 1. Provide COVID-19 testing to individuals who report symptoms consistent with COVID-19, who have exposure to someone who has been diagnosed with COVID-19, or who are tested as part of the organization's COVID-19 surveillance testing strategy.
- ☐ Accept 2. Store and handle the testing supplies in accordance with the package insert provided with the testing supplies.
- ☐ Accept 3. Report all test results to the Tennessee Department of Health (TDH) within 24 hours of receiving notification of results (unless a commercial laboratory is used that reports automatically to the State) and report all positive test results to the local health department immediately upon notification of those results. Fax PH1600 form to 615-741-3857. <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/PH-1600.pdf>
- ☐ Accept 4. Record the individual's testing information in an office log that includes the date of testing, the date of the result notification, the result of the test, the source of specimen collection (nasopharyngeal, nasal, saliva, oropharyngeal), the method of specimen collection (health care provider collection, observed self-collection, self-collection), if the individual had known exposure to COVID-19, if the individual was symptomatic at the time of testing, date of onset of symptoms, the date of notification to Tennessee Department of Health (TDH), the date of notification to the local health department if the result was positive, and the date the individual was notified of test results.

AGREEMENT OF UNDERSTANDING (cont'd.)

In addition, the requesting organization:

- ☐ Accept 5. Shall not charge individuals, health insurance plans, or other third-party payers for the test or any testing supplies provided at no cost to the organization.
- ☐ Accept 6. Must report the number of tests conducted each week and the numbers of positive and negative results (aggregate, de-identified data) to COVID19.Testing@tn.gov.
- ☐ Accept 7. Must provide the individual with a written record of their test result and date of testing unless the patient has access to their results via an online portal.
- ☐ Accept 8. Shall assure that all persons participating in the COVID-19 testing program at this organization are made aware of their obligations under the terms of this agreement.
- ☐ Accept 9. Shall not refuse to provide testing to an eligible individual until notified by the State of Tennessee that the testing initiative has been suspended or discontinued.
- ☐ Accept 10. Acknowledges that negative results obtained through rapid antigen testing should be confirmed by molecular-based testing (PCR).

Additional conditions – the testing organization acknowledges that:

- ☐ Accept 11. TDH reserves the right to inspect testing supply inventory at will.
- ☐ Accept 12. TDH reserves the right to recall or redirect issued testing supplies as dictated by the department's outbreak response needs.
- ☐ Accept 13. The timing and amounts for distribution of these testing supplies will be at the sole discretion of TDH.

Medical Director (or Authorized Designee) Signature

Date

INTERNAL USE ONLY

Dr. Lisa Piercey, MD, MBA, FAAP
Commissioner, Tennessee Department of Health

Date

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS

Name of Organization _____

FACILITY # 1

Name of Facility or Practice _____

Address where testing supplies are to be shipped _____

Building, Floor, Suite Number _____

City _____

State _____

Zip Code _____

County _____

POINT OF CONTACT (POC)

Name _____

Credentials _____

Title _____

() -
Phone

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Fax

E-mail

FACILITY # 2

Name of Facility or Practice _____

Address where testing supplies are to be shipped _____

Building, Floor, Suite Number _____

City _____

State _____

Zip Code _____

County _____

POINT OF CONTACT (POC)

Name _____

Credentials _____

Title _____

() -
Phone

() -
Fax

E-mail

FACILITY # 3

Name of Facility or Practice _____

Address where testing supplies are to be shipped _____

Building, Floor, Suite Number _____

City _____

State _____

Zip Code _____

County _____

POINT OF CONTACT (POC)

Name _____

Credentials _____

Title _____

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Phone

() -
Fax

E-mail

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS (cont'd.)

Name of Organization

FACILITY # 4

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail

FACILITY # 5

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail

Tennessee Department of Health (TDH) • Communicable and Environmental
Diseases and Emergency Preparedness (CEDEP) Vaccine-Preventable Diseases and
Immunization Program (VPDIP) • Vaccines For Children Program (VFC)
710 James Robertson Pkwy • AJT, 3rd Floor • Nashville, TN 37243
Tel: 800-404-3006 • 615-741-7247 • Fax: 615-532-8526 • www.tn.gov/health/cedep/immunization-program.

NAME AND TELEPHONE NUMBER OF
PERSON RESPONSIBLE FOR SHIPMENT:

Overpack



BIOLOGICAL SUBSTANCES
CATEGORY B

Swab Instructions

Self-swab nasal specimen collection

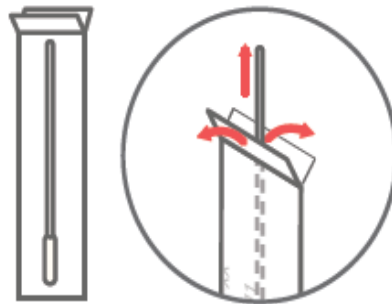
We know you aren't feeling well. Thank you for your participation. With your help, we want to understand whether people can test themselves for COVID-19 without assistance from a clinician.

These kinds of tests could one day become available for at-home swabbing for COVID-19 and other diseases like it. We appreciate your time and attention to the instructions below.

1 Open nasal swab

Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart (like you would to open a band-aid).

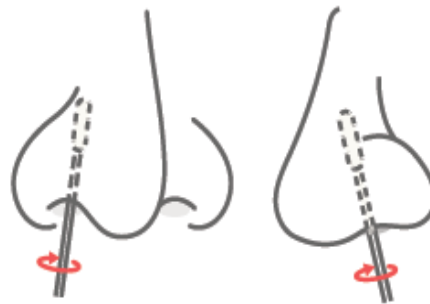
Be careful to only touch the handle, not the tip.



2 Swab nose

Gently insert the **entire** soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle around your nostril **4 times**.

Next, gently insert **the same swab** into the other nostril and rub it around the same way.

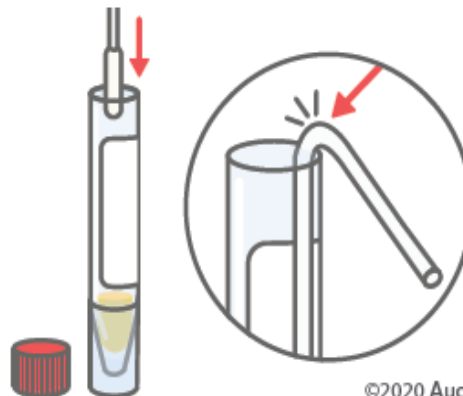


3 Put swab in tube

Lower the swab, tip first, into the provided tube.

Once the tip is at the bottom, break the swab handle at the top of the tube by bending back and forth.

Screw the red cap on tightly.





IMPORTANT: Follow all directions carefully to ensure an adequate specimen is collected for testing.

Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva specimen. Do not remove the plastic film on the tube's funnel.

You can find additional guidance at:

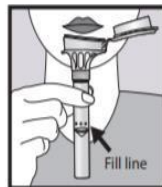
Collection steps: <https://www.dnagenotek.com/US/support/collection-instructions/omnigene-oral/om-505.html>

Collection video: <https://www.youtube.com/watch?v=l0bkXhjPVIU>

Step 1. Specimen collection

1. **IMPORTANT:** Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.
2. Open your P23 At-Home Covid-19 Test Collection Kit and place all of the contents on a clean, dry surface.
3. Remove the saliva collection device from its packaging and collect your specimen.

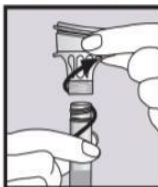
Read complete instructions prior to providing a saliva specimen.



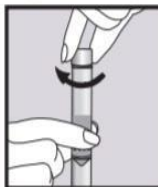
1 Spit until the amount of saliva (not bubbles) reaches the fill line.



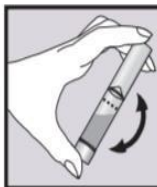
2 Close lid tightly by pushing down hard on the funnel lid until you hear a loud click.



3 Unscrew the funnel from the tube.



4 Use small cap to close tube tightly.



5 Shake the capped tube for 5 seconds.



**KIT P23 DE RECOLECCIÓN PARA PRUEBA DE COVID-19 EN CASA
SALIVA – BAJO LA SUPERVISIÓN DE UN PROFESIONAL MÉDICO
INSTRUCCIONES PARA LOS PACIENTES**

ÚNICAMENTE PARA USO
CON RECETA MÉDICA
ÚNICAMENTE PARA
DIAGNÓSTICO IN VITRO
ÚNICAMENTE CON
AUTORIZACIÓN DE USO
DE EMERGENCIA

Paso 1. Responda el Cuestionario médico sobre la COVID-19 y obtenga una receta para el Kit P23 de recolección para prueba de COVID-19 en casa

El proceso comienza cuando el profesional médico pide un Kit P23 de recolección para prueba de COVID-19 en casa para usted y programa una cita para recolectar una muestra.

Cuando el profesional médico pide el Kit P23 de recolección para prueba de COVID-19 en casa se inicia una de dos opciones:

- El mismo profesional médico le entregará directamente a usted un Kit P23 de recolección para prueba de COVID-19 en casa y el material para envío; o bien
- Al día siguiente, P23 Lab le enviará a su casa un Kit P23 de recolección para prueba de COVID-19 en casa después de haber autenticado el pedido (Paso 2 a continuación). Se requerirá una dirección de correo electrónico válida.



Paso 2. Autentifique su pedido

- Ingresa al sitio web de P23 Lab, www.P23Labs/covid19
- Para comprobar su identidad, cargue su licencia de conducir o una foto suya actual.
- Aparecerá un mensaje que le pedirá que conteste la siguiente pregunta:

¿Decidió usted recibir un Kit P23 de recolección para prueba de COVID-19 en casa a través del consultorio del profesional médico?

Si la respuesta es sí, ¿tiene una cita programada para la recolección supervisada de la muestra?

La recolección de la muestra y su empaquetado deberán ser bajo la supervisión de un profesional médico.

Si la respuesta es no, comuníquese con su profesional médico para programar una cita para recolectar la muestra.

- Si se requiere un pago, le solicitarán que lo haga en este momento.

Paso 3. Reciba en su hogar el Kit P23 de recolección para prueba de COVID-19 en casa

Una vez que haya recibido el Kit P23 de recolección para prueba de COVID-19 en casa, siga los pasos siguientes:

- Ingresa al sitio web de P23 Lab, www.P23Labs/register
- Revise el Kit P23 de recolección para prueba de COVID-19 en casa para asegurarse de que incluya todos los componentes.



Kit P23 de recolección para prueba de COVID-19 en casa

- Ubique en el tubo para recolección el código de barras exclusivo de 14 dígitos y con el código de barras registre el kit en el portal seguro para los pacientes.



IMPORTANTE: siga con cuidado todas las instrucciones para garantizar que se recolecte una muestra adecuada para analizarla.

No recolecte su muestra hasta cuando tenga la cita programada con su profesional médico. NO coma, beba, fume ni mastique chicle durante 30 minutos antes de dar la muestra de saliva. No retire la película de plástico del embudo del tubo.

Para preguntas a cualquier hora, llame a la línea de ayuda del laboratorio al 901-341-6464. Nuestros profesionales están disponibles para orientarlo.

www.p23labs.com P23 Labs, 500 S. University Ave., Suite 504, Little Rock, AR 72205

- Esta prueba no ha sido homologada ni aprobada por la FDA;
- Esta prueba ha sido autorizada por la FDA mediante una EUA (autorización de uso de emergencia) para que la usen los laboratorios autorizados;
- Esta prueba ha sido autorizada únicamente para detectar el ácido nucleico del SARS-CoV-2 y no para ningún otro virus o patógeno; y
- Esta prueba solo está autorizada mientras dure la declaración de que existen circunstancias que justifican la autorización de uso de emergencia de pruebas de diagnóstico in vitro para la detección y/o diagnóstico de la COVID-19 conforme a la Sección 564(b) (1) de la Ley, sección 360bbb-3(b)(1) del Título 21 del U.S.C., a menos que la autorización se dé por concluida o se revoque antes.



KIT P23 DE RECOLECCIÓN PARA PRUEBA DE COVID-19 EN CASA SALIVA – BAJO LA SUPERVISIÓN DE UN PROFESIONAL MÉDICO INSTRUCCIONES PARA LOS PACIENTES

ÚNICAMENTE PARA USO
CON RECETA MÉDICA
ÚNICAMENTE PARA
DIAGNÓSTICO IN VITRO
ÚNICAMENTE CON
AUTORIZACIÓN DE USO
DE EMERGENCIA



IMPORTANTE: NO coma, beba, fume ni mastique chicle durante 30 minutos antes de dar la muestra de saliva.

Los profesionales médicos capacitados conforme a 49CFR 172.700 pueden encontrar más orientación en:

Pasos para la recolección: <https://www.dnagenetek.com/us/support/collection-instructions/omnigene-oral/om-505.html>

Video sobre la recolección: <https://www.youtube.com/watch?v=lobkxhjvlu>

Paso 1. Cita para la recolección

Durante la cita, bajo la supervisión de su profesional médico, usted tomará una muestra de su saliva.

Nota: Esto puede hacerse en persona en el consultorio del profesional médico, o bien en línea a través de una consulta de telemedicina.

Paso 2. Recolección de la muestra

Realice la recolección de la muestra bajo la guía de su profesional médico:

- IMPORTANTE:** Lávese **muy bien las manos durante 20 segundos** y después séqueselas **antes** de empezar la recolección.
- Abra el Kit P23 de recolección para prueba de COVID-19 en casa y coloque todo el contenido sobre una superficie limpia y seca.
- Saque de su empaque el dispositivo para recolección de saliva y recolecte la muestra.



Antes de dar la muestra de saliva, lea todas las instrucciones.



1 Escupa hasta que la cantidad de saliva (no burbujas) llegue a la línea de llenado.



2 Cierre la tapa firmemente presionando con fuerza sobre la tapa del embudo hasta que oiga un clic fuerte.



3 Desarróscalo al embudo del tubo.



4 Utilice la tapa pequeña para cerrar herméticamente el tubo.



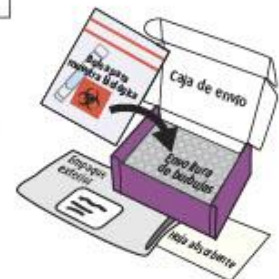
5 Agite durante 5 segundos al tubo tapado.

- IMPORTANTE:** Lávese **muy bien las manos otra vez durante 20 segundos** y séqueselas **después** de haber hecho la recolección.

Paso 3. Preparación de la muestra con su profesional médico para enviarla

- Asegúrese de que la tapa del tubo de la muestra esté cerrada firmemente.
- Ponga la muestra dentro de la bolsa para muestra biológica y haga presión a lo largo del cierre.
- Siga las instrucciones del profesional médico para colocar la bolsa con la muestra en la envoltura de burbujas de protección y dentro de la caja de envío. Ponga encima la hoja absorbente y cierre la tapa de la caja de envío.
- IMPORTANTE:** Lávese **muy bien las manos otra vez durante 20 segundos** y luego séqueselas **después** de terminar la preparación para envío.
- La caja de envío va dentro del empaque exterior etiquetado; retire el protector del adhesivo; cierre y selle el empaque exterior.
- Lleve la caja sellada con empaque exterior que contiene su muestra, a la oficina más cercana de FedEx o UPS, según lo indique la etiqueta de envío con la dirección de P23 Lab.

IMPORTANTE: Lleve la caja a la oficina de paquetería en un plazo de 24 horas después de haber recolectado la muestra.

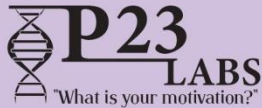


- Esta prueba no ha sido homologada ni aprobada por la FDA;
- Esta prueba ha sido autorizada por la FDA mediante una EUA (autorización de uso de emergencia) para que la usen los laboratorios autorizados;
- Esta prueba ha sido autorizada únicamente para detectar el ácido nucleico del SARS-CoV-2 y no para ningún otro virus o patógeno; y
- Esta prueba solo está autorizada mientras dure la declaración de que existen circunstancias que justifican la autorización de uso de emergencia de pruebas de diagnóstico in vitro para la detección y/o diagnóstico de la COVID-19 conforme a la Sección 564(b)(1) de la Ley, sección 360bbb-3(b)(1) del Título 21 del U.S.C., a menos que la autorización se dé por concluida o se revoque antes.

Paso 4. El resultado está listo en un plazo de 72 horas

Su profesional médico se comunicará con usted cuando tenga el resultado.

Para preguntas a cualquier hora, llame a la línea de ayuda del laboratorio al 901-341-6464. Nuestros profesionales están disponibles para orientarlo.



KIT P23 DE RECOLECCIÓN PARA PRUEBA DE COVID-19 EN CASA
SALIVA – SIN SUPERVISIÓN – INSTRUCCIONES PARA LOS PACIENTES
IMPORTANTE: POLÍTICAS SOBRE LAS PRUEBAS DE COVID-19

ÚNICAMENTE PARA USO
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DIAGNÓSTICO IN VITRO
ÚNICAMENTE CON
AUTORIZACIÓN DE USO
DE EMERGENCIA

Se requiere que los pacientes reúnan requisitos específicos para que puedan recibir la prueba del coronavirus (COVID-19).

Los siguientes criterios que recomienda el Centro para el Control de Enfermedades (CDC) ayudan a que P23 Labs conserve sus pruebas limitadas. El autoconfinamiento es el método más efectivo para evitar que se propague el virus.

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>

¿Quién debe considerar hacerse la prueba de la COVID-19?

- Si se siente gravemente enfermo, busque de inmediato atención médica con un profesional médico.
- Si considera que tiene una emergencia médica, llame al 9-1-1.
- Entre los signos de enfermedad grave están: falta intensa de aliento o dificultad para respirar, tos con sangre, dolor en el pecho, latidos irregulares del corazón, vómitos o diarrea constantes.

El Kit P23 de recolección para prueba de COVID-19 en casa podría ser lo correcto para usted si:

- Actualmente presenta síntomas de COVID-19.
- Vive en un área donde se haya propagado la COVID-19 o recientemente ha viajado a un área donde se haya propagado.
- Ha tenido contacto estrecho con alguna persona que se sepa que tiene la COVID-19.
- Piensa que ha estado expuesto a la COVID-19.
- **Nota:** Este Kit P23 de recolección para prueba de COVID-19 en casa puede usarse para que un proveedor de atención médica recolecte la saliva, para autorrecolección en un centro médico, para autorrecolección en casa a través de una consulta de telemedicina y para autorrecolección en casa sin supervisión.

El Kit P23 de recolección para prueba de COVID-19 en casa podría NO ser lo correcto para usted si:

- Actualmente tiene síntomas graves que le limitan sus actividades diarias. Si ese es el caso, busque atención médica de inmediato.
- No tiene síntomas y no ha estado expuesto a la COVID-19.
- No tiene síntomas y no ha estado en un área donde se haya propagado la COVID-19.



¿Cómo funciona el Kit P23 de recolección para prueba de COVID-19 en casa?

El Kit P23 de recolección para prueba de COVID-19 en casa le brinda una forma de hacerse la prueba en la comodidad y seguridad de su propio hogar mediante una muestra de saliva. Para obtener la prueba de COVID-19 no es necesario ir al consultorio del médico ni consultar con otro proveedor de atención.

- 1 Conteste el Cuestionario médico sobre la COVID-19:** Ingrese a www.P23Labs/covid19 para responder en línea un breve cuestionario de salud para determinar su riesgo de contraer la enfermedad.
- 2 Pida el kit:** Adquiera en el sitio web el Kit P23 de recolección para prueba de COVID-19 en casa. Una vez que haya hecho su pedido, P23 Labs le enviará a su casa el kit de la prueba de COVID-19 registrado con su código de barras exclusivo.
- 3 Recolecte la muestra:** El Kit P23 de recolección para prueba de COVID-19 en casa incluye todo lo necesario para recolectar la muestra de saliva e instrucciones fáciles de comprender. Para saber más sobre cómo recolectar la muestra, vea el video (el vínculo aparece en la página siguiente).
- 4 Envíela al laboratorio:** Después de que haya recolectado la muestra, envíela en el empaque prepago en un plazo de 24 horas después de que la haya recolectado, para que se analice. Lleve la caja empacada y sellada con su muestra a la oficina más cercana de FedEx, UPS u otra compañía de paquetería autorizada, ANTES de la última recogida del día.
- 5 Obtenga el resultado:** Cuando su resultado esté listo, recibirá un aviso por correo electrónico y podrá verlo en línea en su cuenta protegida de P23. Después de que haya recibido el resultado de la COVID-19, tendrá oportunidad de hablar con un médico autorizado que podrá responderle las preguntas que pudiera tener.





**KIT P23 DE RECOLECCIÓN PARA PRUEBA DE COVID-19 EN CASA
SALIVA – BAJO LA SUPERVISIÓN DE UN PROFESIONAL MÉDICO
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ÚNICAMENTE PARA USO
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IMPORTANTE: NO coma, beba, fume ni mastique chicle durante 30 minutos antes de dar la muestra de saliva.

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Durante la cita, bajo la supervisión de su profesional médico, usted tomará una muestra de su saliva.

Nota: Esto puede hacerse en persona en el consultorio del profesional médico, o bien en línea a través de una consulta de telemedicina.

Paso 2. Recolección de la muestra

Realice la recolección de la muestra bajo la guía de su profesional médico:

- IMPORTANTE:** Lávese muy bien las manos durante 20 segundos y después séqueselas antes de empezar la recolección.
- Abra el Kit P23 de recolección para prueba de COVID-19 en casa y coloque todo el contenido sobre una superficie limpia y seca.
- Saque de su empaque el dispositivo para recolección de saliva y recolecte la muestra.



Antes de dar la muestra de saliva, lea todas las instrucciones.



1 Escupa hasta que la cantidad de saliva (no burbujas) llegue a la línea de llenado.



2 Cierre la tapa firmemente presionando con fuerza sobre la tapa del embudo hasta que oiga un clic fuerte.



3 Desenrosque el embudo del tubo.



4 Utilice la tapa pequeña para cerrar herméticamente el tubo.



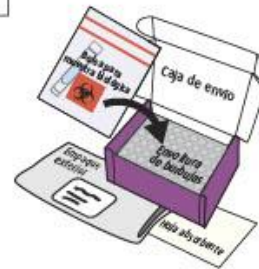
5 Agite durante 5 segundos el tubo tapado.

- IMPORTANTE:** Lávese muy bien las manos otra vez durante 20 segundos y séqueselas después de haber hecho la recolección.

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Paso 4. El resultado está listo en un plazo de 72 horas

su profesional médico se comunicará con usted cuando tenga el resultado.

Para preguntas a cualquier hora, llame a la línea de ayuda del laboratorio al 901-341-6464. Nuestros profesionales están disponibles para orientarlo.